UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

December 21, 2012

MEMORANDUM:

Subject:	Name of Pesticide Product:	AQUASHADE-PLUS
	EPA Reg. No. /File Symbol:	33068-G
	DP Barcode:	DP 407700
	Decision No.:	465576
	Action Code:	R310
	PC Code:	110301 (Acid Blue 9: 30.45%) 110302 (1-H-Pyrazole-3-carboxylic acid, 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-((4-sulfophenyl)azo)-, Trisodium salt: 2.45%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Dec. 21, 2012

M Hoshin
Team Leader/Tox

To: Grant Rowland/Kathryn Montague RM 23
Herbicide Branch
Registration Division (7505P)

Registrant: AQUASHADE (a LONZA Company)

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
110301 Erioglaucine	30.45%
110302 Tartrazine	2.45%
Other Ingredient(s):	67.10%
TOTAL	100.00%

Contains 2.92 lbs of erioglaucine and 0.235 tartrazine per gallon.

ACTION REQUESTED: "This is the Tox review we discussed… Please conduct your review to determine if the Toxicity data is acceptable. I have included: cited CSF; data matrix; proposed CSF; waiver justification; the tox data MRIDs; cover letter; label…"

COMMENTS AND RECOMMENDATIONS:

1. The five acute toxicity studies (MRIDs 48845404, 48845405, 48845406, 47318606, 47318607) have been classified as acceptable. In addition, after reviewing the 12/18/2012 email from John French (of Lonza) to Grant Rowland, TRB recommends for a waiver of the inhalation study requirement for this formulation with assignment to EPA Toxicity Category IV by this exposure route. This recommendation is based on the fact that the actives are food grade dyes with relatively little (or no) toxicity. In addition, TRB notes that the dyes are also water soluble so any dye material getting into the respiratory tract will not be permanent. These studies (and the acute inhalation study waiver) satisfy the acute toxicity data requirements for the registration of EPA File Symbol 33068-G.

2. Based on the results of the five studies and inhalation study waiver (with assignment to EPA Toxicity Category IV by the inhalation route), the following is the acute toxicity profile of EPA File Symbol 33068-G:

Acute oral toxicity	IV	Acceptable	MRID 48845404
Acute dermal toxicity	IV	Acceptable	MRID 48845405
Acute inhalation toxicity	(IV)	Waived	
Primary Eye irritation	IV	Acceptable	MRID 48845406
Primary Dermal Irritation	IV	Acceptable	MRID 47318606
Dermal Sensitization	Negative	Acceptable	MRID 47318607

3. Based on the acute toxicity profile as well as information from the Confidential Statement of Formula and the uses indicated on the proposed label, the following is the precautionary and first aid labeling for 33068-G as obtained from the TRB Label Review System:

PRODUCT ID #: **033068-00003**

PRODUCT NAME: **AQUASHADE-PLUS**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: **CAUTION (optional)**

Hazards to Humans and Domestic Animals:

[No statements required. The registrant has the option of using toxicity category III statements to address one or more exposure routes].

First Aid:

[No statements required. The registrant has the option of using toxicity category III first aid statements to address one or more exposure routes].

4. The TRB Chemistry Team should review and accept the CSF dated May 29, 2012.

Reviewer: Byron T. Backus, Ph.D. **Date:** December 21, 2012
Risk Manager (EPA): 23

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies (and inhalation study waiver request) submitted to support the proposed product, File Symbol 33068-G:

1. DP BARCODE: 407700				
2. PC CODES: 110301, 110302				
3. CURRENT DATE: December 21, 2012				
Test material: Aquashade Concentrate, Lot #05152007, containing Hidacid Azure Blue 50% Dye: 90.91% and Tartrazine Solution 28% Dye: 9.09%. Described as a dark blue liquid with a density of 1.16 g/mL. Note: Hidacid Azure Blue 50% Dye 90.91% = Erioglaucine 45.46%; Tartrazine Solution 28% Dye 9.09% =				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity / rat Eurofins Product Safety Labs, Dayton NJ / Lab Study No. 22363/ August 23, 2007 / OCSPP 870.1100; OECD 425	48845404	LD_{50} (F) > 5000 mg/kg; no deaths or signs of toxicity in 3/3F dosed at 5000 mg/kg. All gained wt days 0-7 & 7-14. No gross abnormalities at necropsy.	IV	A
Acute dermal toxicity / rat Eurofins Product Safety Labs, Dayton NJ / Lab Study No. 22364 / August 23, 2007/ OCSPP 870.1200; OECD 402	48845405	LD_{50} > 5000 mg/kg (both sexes) No deaths, abnormal systemic effects, or abnormal gross findings. All gained wt days 0-7 & 7-14. All had blue staining at the application site.	IV	A
Acute inhalation toxicity / rat Data waiver request OCSPP 870.1300; OECD 403	--------	Actives are food grade dyes with relatively little (or no) toxicity. The dyes are also water soluble so any dye material getting into the respiratory tract will not be permanent. Waiver is appropriate with assignment to Tox. Cat. IV for inhalation.	(IV)	W
Primary eye irritation / rabbit Eurofins Product Safety Labs, Dayton NJ / Lab Study No. 22365 / August 23, 2007 OCSPP 870.2400; OECD 405	48845406	Eyes were anesthetized before instillation. No corneal opacity or iritis. All eyes had grade 2 conjunctival redness at 1 hour, but all eyes had only grade 1 redness (not considered positive for irritation) at 24, & 48 hrs. There was grade 2-3 discharge at 1 & 24 hrs and blue staining around eye at 1, 24, 48 & 72 hrs. All scores zero at 72 hrs. MMTS=12.0 at 1 hour.	IV	A

Primary dermal irritation / rabbit Eurofins Product Safety Labs, Dayton NJ / Lab Study No. 22366 / August 23, 2007 OCSPP 870.2500; OECD 404	47318606	Reactions scored at 30-60 min., 24, 48, and 72 hours. At 30-60 min and 24 hrs 3/3 scored 1 for erythema and 0 for edema; at 48 hrs 2/3 scored 1 for erythema and zero for edema. At 72 hrs all scores were zero. There was blue staining at the application site at all times. PDII = 0.75.	IV	A
Dermal sensitization / guinea pig (Buehler method) Eurofins Product Safety Labs, Dayton NJ / PSL No. 22367 / September 21, 2007 OCSPP 870.2600; OECD 406	47318607	Undiluted test material used for induction, 50% w/w in distilled water used for challenge. 0/20 guinea pigs showed a positive response (score of 1.0 or greater) at 24 & 48 hours after challenge. There was blue staining at the dose sites. 7/10 showed a positive response to αHCA in positive control assay (study completed May 12, 2007).	Not a sen-si-tizer	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap
n/a = "not applicable"